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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,996	01/13/2004	Peter M. Bonutti	780-A03-021-5	1472

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MIAMI, FL 33180

EXAMINER

REIP, DAVID OWEN

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/755,996	Applicant(s) BONUTTI, PETER M.	
	Examiner David O. Reip	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-10 and 13-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/27/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 8, 9, and 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (U.S. Pat. No. 5,609,635) in view of Heggeness et al (U.S. Pat. No. 5,514,180). Michelson shows several embodiments of tapered implantable devices "for changing the special relationship between first and second bones" (note col.6, lines 29-33, "The angular relationship of the upper and lower surfaces 112 and 114 places and maintains the vertebrae adjacent to those surfaces in an angular relationship, *creating* and maintaining the desired lordosis of the spine." Further, in col. 10, lines 45-49, "...the contour of that specialized insertion end of the implant 400 is such that it then allows for a ramping up of the adjacent vertebrae relative to the implant 400 as the implant is advanced forward into the disc space."). Further, see cols. 7 and 9, for disclosure to embodiments coated with BMP as well as other fusion enhancing materials. See the embodiments of Figs. 9-16 showing open cellular/porous structure. See the embodiment of Fig. 31 showing "fastener means" 708 and comprising at least one screw 718. See the embodiments of Figs. 2, 8, and 13 showing implants having round side surfaces 130/330 "corresponding to at least an outer side surface of one of the first and second bones." However, Michelson does not specifically show the devices having first and second channels with corresponding screws. Fig. 27 of Heggeness et al teaches a similar implant having first and second channels (102 and

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103) and corresponding screws 107, the screws providing additional means for securing the device between the vertebrae. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify any of the Michelson embodiments to include channels and screws, as taught by Heggeness et al, as an additional means for securing the implants to the vertebral bodies.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of Heggeness et al, and further in view of Jefferies (U.S. Pat. No. 4,394,370). Michelson as modified by Heggeness et al discloses apatite compositions, but does not specifically disclose demineralized bone powder and collagen. Jefferies teaches both demineralized bone powder and collagen as bone graft material. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include demineralized bone powder and collagen as suitable substances for use in a coating on the Michelson implants, since those substances are well-known and are in common use in the art of bone fusion, providing the known advantage of enhancing bone growth around and into implants.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of Heggeness et al, and further in view of Zdeblick et al (U.S. Pat. No. 5,669,909). Michelson as modified by Heggeness et al discloses open cellular and biocompatible material, but does not specifically disclose tantalum. Zdeblick et al teaches porous tantalum which allows bone ingrowth. Therefore, it would have been

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obvious to one of ordinary skill in the art at the time the invention was made to use tantalum, as taught by Zdeblick et al, as a material of construction for any of the open cellular/porous embodiments of Michelson, since tantalum is known and preferred in the art of fusion implants for its good mechanical properties and biocompatibility.

The courts have concluded that there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). Also, references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip whose telephone number is 571-272-4702. The examiner can normally be reached on 7 A.M.- 4:30 P.M. Mon-Thu and every other Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David O. Reip
Primary Examiner
AU 3733